



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,460	11/24/2003	Shigeo Ohno	2352.002	6486

23405 7590 01/22/2008
HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
----------	--------------

1656

MAIL DATE	DELIVERY MODE
-----------	---------------

01/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/720,460

Applicant(s)

OHNO, SHIGEO

Examiner

David J. Steadman

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/07 has been entered.

[2] Claims 1, 3, and 17 are pending in the application.

[3] Applicant's amendment to the claims, filed on 10/29/07, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[4] Applicant's arguments filed on 10/29/07 in response to the Office actions mailed on 10/22/07 and 4/27/07 are acknowledged. Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim to Domestic and Foreign Priority

[6] As noted in a prior Office action, applicants' claim to domestic priority under 35 U.S.C. § 120 to PCT/JP01/10234, filed 22 November 2001, is acknowledged.

Art Unit: 1656

Applicant's claim to foreign priority under 35 U.S.C. § 119(a)-(d) to Japanese application JP 2001-156088, having the priority date of 24 May 2001, is acknowledged. A certified copy of the foreign priority document has been filed in the instant application on 10/20/06 and an English-language translation of Japanese application JP 2001-156088 has been filed in the instant application on 3/20/07.

Specification/Informalities

[7] The specification is objected to as failing to satisfy the requirements for a sequence listing. See particularly p. 66, middle, which discloses the sequence of an HA peptide. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicants should identify nucleotide sequences of at least 10 nucleotides and amino acid sequences of at least 4 amino acids in the specification by a proper sequence identifier, i.e., "SEQ ID NO:" (see MPEP 2422.01). If these sequences have not been listed in the computer readable form and paper copy of the sequence listing, applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper

and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d).

Claim Objection

[8] As noted in a previous Office action, the specification defines "SMG-1 activity" as being "an activity of phosphorylating Upf1/SMG-2 [Sun, X. et al., Proc. Natl. Acad. Sci. USA, 95, 10009-10014 (1998); and Bhattacharya, A. et al., RNA, 6, 1226-1235 (2000)]" (specification at p. 6, middle). Regarding the specification's definition of "SMG-1 activity," MPEP 2111.01.IV states, "[w]here an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999)." Although "SMG-1 activity" is specifically defined and limited to the definition provided above, which is undisputed by applicant, claim 1 is objected to in the recitation of "SMG-1...activity" and in order to improve claim form, it is suggested that the phrase ", wherein SMG-1 activity is phosphorylating Upf1/SMG-2 and wherein the polypeptide comprises" be inserted following "having SMG-1...activity and comprising" in claim 1.

Claim Rejections – 35 U.S.C. 112, First Paragraph

[9] Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the polypeptide of claim 1, does not reasonably provide enablement for all agents for promoting non-sense

Art Unit: 1656

mediated mRNA decay, comprising the polypeptide of claim 1 as encompassed by the claims for reasons that follow. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

According to MPEP 2164.08, "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation" (emphasis added). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

The breadth of the claims: According to MPEP 2164.04, "[b]efore any analysis of enablement can occur, it is necessary for the examiner to construe the claims...and explicitly set forth the scope of the claim when writing an Office action." Also, MPEP 2164.08 states, "[a]ll questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of

the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims...claims are to be given their broadest reasonable interpretation that is consistent with the specification."

Claim 17 is drawn to an "agent for promoting nonsense-mediated RNA decay", comprising the polypeptide of claim 1. According to the specification, "The substance promoting the SMG-1 activity...can promote [non-sense mediated mRNA decay], and is useful as a candidate of an agent for treating and/or preventing a disease caused by mRNA having one or more [premature translation termination codons]...the substance promoting SMG-1...may be administered alone, or preferably, together with a pharmaceutically or veterinarily acceptable ordinary carrier or diluent, to a subject (for example, an animal, preferably a mammal, particularly a human) in need of promoting NMD, or in need of treating and/or preventing a disease caused by mRNA having one or more PTCs...in an effective dosage (p. 36, paragraphs 2-3). In view of this disclosure, the claimed "agent for promoting nonsense-mediated mRNA decay" has been interpreted in light of the specification as encompassing a therapeutic agent for use in "treating and/or preventing a disease caused by mRNA having one or more [premature translation termination codons]".

The enablement provided by the specification is not commensurate in scope with the claims with regard to broad scope of "agents" encompassed by the claims. In this case, the specification is enabling only for a composition comprising the polypeptide of claim 1.

The amount of direction provided by the inventor and The existence of working examples: The specification, while disclosing the polypeptide of SEQ ID NO:2, fails to provide the necessary guidance for using SEQ ID NO:2 as a therapeutic agent. For example, the specification fails to provide even a single working example where the polypeptide of SEQ ID NO:2 was administered to a "patient" to achieve a therapeutic effect against a disease caused by mRNA having one or more PTCs, particularly preventing such a disease as encompassed by the claims. The specification fails to provide guidance regarding those diseases that are "caused by mRNA having one or more PTCs" and fails to provide guidance regarding *inter alia* the route and method of administration, the dosage, and the composition of the agent that will successfully achieve a therapeutic or preventative effect.

The state of the prior art; The level of one of ordinary skill; and The level of predictability in the art: There is no evidence in the prior art of record that an SMG-1 polypeptide can be used to treat and/or prevent diseases that are "caused by mRNA having one or more PTCs" and there is no evidence in the prior art of record of those diseases that can be treated using an SMG-1 polypeptide. Moreover, based upon the post-filing reference of Usuki et al. (*Mol. Ther.* 14:351-360, 2006), it appears that by abolishing – not promoting – the activity of SMG-1, which has the result of inhibiting NMD has therapeutic potential. See p. 351, abstract. As such, because neither the specification nor the prior art provides guidance for using SMG-1 as a therapeutic agent in "promoting NMD" to treat and/or prevent diseases that are "caused by mRNA having one or more PTCs", there is no guidance in the specification or the prior art of record

regarding those diseases that can be treated using an SMG-1 polypeptide by “promoting NMD”, and the post-filing art suggests that abolishing SMG-1 activity – not promoting it – potentially has a therapeutic effect, it is highly unpredictable as to whether or not SMG-1 can be used as a therapeutic to treat and/or prevent diseases that are “caused by mRNA having one or more PTCs”.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure: While methods of treating diseases using polypeptide therapeutic agents were known in the art at the time of the invention, it was not routine in the art to first identify whether or not a polypeptide could be so useful, identifying those diseases that can be treated and/or prevented using the polypeptide. As such, the amount of experimentation required to make and use the full scope of claim 17 would require undue experimentation.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability, and the quantity of experimentation, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly,

extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

[10] The rejection of claims 1, 3, and 17 under 35 U.S.C. 102(b) as being anticipated by Ohnishi et al. ("22nd Annual Meeting of the Molecular Biology Society of Japan," Program and Abstracts, December 7-10, 1999; cited as reference CC* in the IDS filed 8/3/06) is withdrawn, not in view of applicant's arguments, but upon further consideration and in favor of the rejections as set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

[11] Claim(s) 1, 3, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohnishi et al. ("22nd Annual Meeting of the Molecular Biology Society of Japan," Program and Abstracts, December 7-10, 1999, Abstract only, published 11/22/99; cited as reference CC* in the IDS filed 3 August 2006; "Ohnishi (abstract only)") in view of Hibi et al. (*Genes Develop.* 7:2135-2148, 1993; "Hibi"). For purposes of clarification, it is

noted that the instant rejection is based on the Ohnishi *abstract only*, i.e., pp. 14-16 of the Ohnishi reference filed on 8/3/06, not the oral presentation slides.

Claim 1 is drawn to an isolated polypeptide comprising amino acids 129 to 3657 of SEQ ID NO:2, or a variant thereof having 1-5 amino acids altered. Claim 3 is drawn to a polypeptide consisting of amino acids 1 to 3657, amino acids 107 to 3657 or amino acids 129 to 3657 of SEQ ID NO:2. Claim 17 is drawn to an agent for promoting nonsense-mediated mRNA decay, comprising the polypeptide of claim 1.

Ohnishi (abstract only) teaches isolation of a "PI3K-related protein kinase" having the following disclosed features: 1) kinase activity; 2) present in HeLa cell extracts; 3) a molecular weight of 430 or 400 kilodaltons; 4) phosphorylates p53 at Ser15 and Ser37 *in vitro*; and 5) exhibits autophosphorylation activity that is wortmannin-sensitive. Ohnishi (abstract only) teaches "It was pointed out that these [p53] phosphorylation sites play an important role in regulation of the p53 function against DNA damage". Ohnishi (abstract only) does not expressly teach methods for isolating the disclosed polypeptide from a HeLa cell extract.

Hibi teaches a method for identifying and purifying a kinase polypeptide (JNK) from a cell extract, including HeLa cells, using a known substrate polypeptide (c-Jun) with recognized phosphorylation sites (Ser63 and Ser73) of the JNK polypeptide. See particularly the methodology set forth at p. 2136, column 1 to p. 2141, column 1.

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Ohnishi (abstract only) and Hibi to isolate the polypeptide discussed in Ohnishi (abstract only) using the methodology of

Hibi. One would have been motivated to do this since Ohnishi (abstract only) specifically discloses a desire to isolate the polypeptide, particularly as it phosphorylates two residues of p53 that "play an important role in regulation of the p53 function against DNA damage" as noted above. One would have a reasonable expectation of success for isolating the polypeptide discussed in Ohnishi (abstract only) because of the results of Ohnishi (abstract only), which provides a characterization of the polypeptide, including the features noted above, which would have provided distinguishing characteristics of the polypeptide and the results of Hibi, which would have provided a well-known methodology for isolating the polypeptide of Ohnishi (abstract only). Therefore, claims 1, 3, and 17, drawn to a polypeptide and agent as described above would have been obvious to one of ordinary skill in the art at the time of the invention.

The following comments are provided to clarify the instant rejection. In this case, the polypeptide of Ohnishi (abstract only) and the polypeptide of SEQ ID NO:2 are both disclosed as being isolated from HeLa cells and having a molecular weight of 400 or 430 kDa (Example 5, beginning at p. 55), having kinase activity (Example 9, beginning at p. 65), phosphorylating p53 at Ser15 *in vitro* (Figure 22); 5) exhibiting autophosphorylation activity (specification at p. 2, bottom); and 6) having kinase activities are wortmannin-sensitive (Example 11, beginning at p. 73, bottom). As such, it is the examiner's position that the polypeptide described by Ohnishi (abstract only) is the same as SEQ ID NO:2 as disclosed herein. While it is acknowledged that Ohnishi (abstract only) does not teach the sequence of the polypeptide, applicant's attention is directed to MPEP 2112, wherein the Court in *In re Crish*, 393 F.3d 1253, 1258, 73

USPQ2d 1364, held that “the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that ‘just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.’”

Also, while it is acknowledged that Ohnishi (abstract only) does not teach the polypeptide as being useful for “suppressing nonsense-mediated mRNA decay” or for “promoting nonsense-mediated mRNA decay,” it is noted that this appears to be an intended use limitation and if the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP 2111.02.II.

Since the Office does not have the facilities for examining and comparing applicant’s protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein or agent). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

[12] Claim(s) 1, 3, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohnishi et al. (“22nd Annual Meeting of the Molecular Biology Society of Japan,” Program and Abstracts, December 7-10, 1999, cited as reference CC* in the IDS filed 3 August 2006; “Ohnishi (oral presentation)”) in view of Hibi et al. (*Genes Develop.*

7:2135-2148, 1993; "Hibi"). Claims 1, 3, and 17 are drawn to polypeptides and an agent as noted above.

The reference of Ohnishi (oral presentation) teaches isolation by immunoprecipitation of a polypeptide referred to as "LICK" from HeLa cell extracts having the following disclosed features: 1) kinase activity; 2) present in HeLa cell extracts; 3) a molecular weight of 430 or 400 kilodaltons; 4) phosphorylates p53 at Ser15 and Ser37 *in vitro*; and 5) exhibits autophosphorylation activity that is wortmannin-sensitive. Ohnishi (oral presentation) teaches "It was pointed out that these [p53] phosphorylation sites play an important role in regulation of the p53 function against DNA damage". Ohnishi (oral presentation) further teaches a 26 amino acid internal amino acid sequence of the LICK polypeptide that appears to be unique to the LICK polypeptide relative to other homologous polypeptides (slide 11). Ohnishi (oral presentation) does not expressly teach methods for isolating the LICK polypeptide from a HeLa cell extract.

The relevant teachings of Hibi are described above.

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Ohnishi (oral presentation) and Hibi to isolate the polypeptide discussed in Ohnishi (oral presentation). One would have been motivated to do this since Ohnishi (oral presentation) specifically discloses a desire to isolate the polypeptide, particularly as it phosphorylates two residues of p53 that "play an important role in regulation of the p53 function against DNA damage" as noted above. One would have a reasonable expectation of success for isolating the

polypeptide discussed in Ohnishi (oral presentation) because of the results of Ohnishi (oral presentation), which provides a characterization of the polypeptide and provides an internal sequence for generating an antibody specific for "LICK" to use in immunoprecipitation or confirmation of the polypeptide's identity, and the results of Hibi, which would have provided a well-known methodology for isolating the polypeptide of Ohnishi (oral presentation). Therefore, claims 1, 3, and 17, drawn to a polypeptide and agent as described above would have been obvious to one of ordinary skill in the art at the time of the invention.

In this case, the polypeptide of Ohnishi (oral presentation) and the polypeptide of SEQ ID NO:2 are both disclosed *inter alia* as being isolated from HeLa cells being 400 or 430 kDa (Example 5, beginning at p. 55), having kinase activity (Example 9, beginning at p. 65), phosphorylates p53 at Ser15 *in vitro* (Figure 22); 5) exhibits autophosphorylation activity (specification at p. 2, bottom); and that the kinase activities are wortmannin-sensitive (Example 11, beginning at p. 73, bottom); and 6) shares an internal sequence that is 100% identical to amino acids 2331 to 2356 of SEQ ID NO:2 herein. As such, it is the examiner's position that the polypeptide described by Ohnishi (oral presentation) is the same as SEQ ID NO:2 herein. While it is acknowledged that Ohnishi (oral presentation) does not teach the sequence of the polypeptide, applicant's attention is directed to MPEP 2112, wherein the Court in *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, held that "the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the

claimed oligonucleotides. The court stated that 'just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.'"

Also, while it is acknowledged that Ohnishi (oral presentation) does not teach the polypeptide as being useful for "suppressing nonsense-mediated mRNA decay" or for "promoting nonsense-mediated mRNA decay," it is noted that this appears to be an intended use limitation and if the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP 2111.02.II.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

RESPONSE TO ARGUMENT: Beginning at p. 4, top of the instant response, applicant argues the oral presentation was a "transient display" and does not constitute a "printed publication" for purposes of 35 U.S.C. 102. Beginning at p. 5, top of the instant response, applicant further argues the Ohnishi reference fails to disclose the amino acid or the encoding nucleotide sequence of the polypeptide and thus one of ordinary skill in the art would not be able to generate an antibody for isolation of the polypeptide. According to applicant, while one could in theory generate an antibody to

the disclosed internal sequence, since the reference did not disclose this region's "conformational location", its specificity and ability to immunoprecipitate the claimed polypeptide does not necessarily follow.

Applicant's argument is not found persuasive. In this case there appears to be no evidence of record that, with the exception of the printed abstract of Ohnishi et al., the additional material filed on 8/3/06 was "disseminated by the distribution of reproductions or copies and/or indexed in a library or database". However, this alone would not appear to preclude the finding that the additional material filed on 8/3/06 is a "printed publication". The Court in *In re Klopfenstein*, 72 USPQ2d 1117 (Fed. Cir. 2004) stated, "the key inquiry is whether or not a reference has been made publicly accessible" and considered the following factors relevant to considering whether or not an oral presentation constitutes a prior art reference: 1) the length of time the display was exhibited, 2) the expertise of the target audience, 3) the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and 4) the simplicity or ease with which the material displayed could have been copied. Regarding 1), there is no evidence of record that would suggest the length of time the display was exhibited, however, since the presentation was asserted to be an oral presentation, it is likely the length of time of display would have been a matter of minutes and not a matter of hours or days. Regarding 2), since the oral presentation was presented at the "Annual Meeting of the Molecular Biology Society of Japan", it is likely that the audience would have been highly skilled in the art of molecular biology and would have desired to attend the presentation based on its abstract. Regarding 3), there is no evidence of

record that the presentation was conducted with any confidentiality restrictions and thus it is presumed the material shown in the slides was available for copying. Regarding 4, since the relevant novel information in slide 11 is a 26 contiguous amino acid sequence that can be abbreviated in one-letter form, it would have been a simple matter to copy the 26 amino acid sequence. Thus, taken as a whole, it is the examiner's position that the slide presentation, even as an oral presentation, would have constituted a "printed publication".

Regarding applicant's argument regarding enablement of the reference, it is noted that the rejection is now based on a combination of references that, when taken as a whole, would have enabled the claimed polypeptide at the time of the invention. While applicant argues there is no expectation that an antibody generated to the 26 amino acid sequence of Ohnishi (oral presentation) could have been used to immunoprecipitate the claimed polypeptide, it is noted that applicant fails to provide any objective evidence to support this conclusion. As noted in MPEP 716.01(c), "The arguments of counsel cannot take the place of evidence in the record". Even assuming *arguendo* applicant provided such evidence, it is noted that there is no requirement that immunoprecipitation be used to isolate the claimed polypeptide. Although the examiner maintains an antibody could have been used for immunoprecipitation of the LICK polypeptide, even if could not, the antibody could still be used to confirm the identity of LICK in a Western blot analysis, since the LICK polypeptide would be present in a denatured form in an SDS-PAGE gel. Also, even assuming *arguendo* the 26 amino acid sequence as shown by Ohnishi (oral presentation) could not be used to generate an

Art Unit: 1656

antibody, as noted above, alternative methods for isolating a kinase polypeptide, given its substrate and target amino acids for phosphorylation, were well-known in the prior art at the time of the invention and would have been used to isolate the claimed polypeptide, even without an antibody to the sequence disclosed in Ohnishi (oral presentation).

Conclusion

[13] Status of the claims:

Claims 1, 3, and 17 are pending.

Claims 1, 3, and 17 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656